K010068 (1 of 2)

FEB - 8 2001

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6207

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification:

Class II, Product Code 79ESW, 21 CFR 878.3610

Common Name:

Esophageal Stent

Proprietary Name:

Rüsch Polyflex Stent for the Esophagus
with Introducer System

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Polyflex Stent for the Esophagus with Introducer System is substantially equivalent to the Boston Scientific Ultraflex™, Boston Scientific Wall Stent, Cook, Inc. Esophageal Z-Stent, and the Wilson-Cook Esophageal Prosthesis Set.

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4. Description of the Device.

The Rüsch Polyflex Stent for the Esophagus with Introducer System consists of the Polyflex Stent, Introducer Sleeve, Stent Loader, Insertion Tube with Dilator, Soft Positioner, Stopper and Stent Clamp.

5. Intended Use of the Device.

The Rüsch Polyflex Stent for the Esophagus with Introducer System intended for use with Esophageal Stenosis, Esophago-respiratory-fistula, and Maintaining esophageal lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors.

6. Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to predicate devices:

The stent is constructed with an integral polyester braid, which is surrounded by medical grade silicone. This is the same construction as Rüsch Polyflex Stent Kit, which was cleared under K 982614.

The product is delivered through the mouth via a delivery system as is the Wilson Cook Esophageal Prosthesis and the Microvasive Ultraflex.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rusch International
50 Plantation Drive
Jaffery, New Hampshire 03452

Re: K010068
Trade Name: Rusch Polyflex Stent for the Esophagus
with Introducer System
Regulatory Class: II
Product Code: ESW
Dated: January 5, 2001
Received: January 8, 2001

Dear Ms. Brozowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K910068

Device Name: Rusch Polyflex Stent for the Esophagus with Introducer System

Indications For Use:

* Esophageal stenoses
* Esophago-respiratory-fistulae
* Maintaining esophageal lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K910068

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1–2–96)